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Ser. No.: **09/310,844** Filing Date: **5/12/99** Docket No.: **IBIS0058-100 (IBIS0017US) (141037)**

Title: **Molecular Interaction Sites Of Interleukin-2 RNA And Methods Of Modulating The Same** Pages to Follow: **6**

Sender's Name: **Paul K. Legaard** Date: **June 30, 2004**

RECIPIENT(S)	COMPANY/FIRM	FAX
Examiner K. Lacourciere	**USPTO**	**(703) 872-9306**

MESSAGE: **OFFICIAL FACSIMILE**

PLEASE DELIVER TO EXAMINER K. LACOURCIERE. ATTACHED IS:

1. Transmittal Form (1 page);
2. Request for Reconsideration (3 pages); and
4. Copy of Advisory Action (3 pages).

IF YOU DO NOT RECEIVE ALL PAGES, PLEASE CALL 215.665.2000 or 800.523.2900 IMMEDIATELY.

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TRANSMITTAL FORM

(to be used for all correspondence after initial filing)

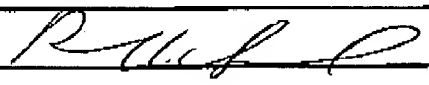
Application Number	09/310,844
Filing Date	May 12, 1999
First Named Inventor	David J. Ecker
Art Unit	1635
Examiner Name	K. Lacourciere
Total Number of Pages In This Submission	Attorney Docket Number: IBIS058-100 (IBIS-0017US)

ENCLOSURES *(check all that apply)*

- ☐ Fee Transmittal Form
  - ☐ Fee Attached
- ☒ Amendment / Reply
  - ☐ After Final
- ☐ Affidavits/declaration(s)
- ☐ Extension of Time Request
- ☐ Express Abandonment Request
- ☐ Information Disclosure Statement
- ☐ Certified Copy of Priority Document(s)
- ☐ Response to Missing Parts/ Incomplete Application
  - ☐ Response to Missing Parts under 37 CFR 1.52 or 1.53
- ☐ Drawing(s)
- ☐ Licensing-related Papers
- ☐ Petition
- ☐ Petition to Convert to a Provisional Application
- ☐ Power of Attorney, Revocation Change of Correspondence Address
- ☐ Terminal Disclaimer
- ☐ Request for Refund
- ☐ CD, Number of CD(s) ____
- ☐ After Allowance Communication to Technology Center (TC)
- ☐ Appeal Communication to Board of Appeals and Interferences
- ☐ Appeal Communication to TC (Appeal Notice, Brief, Reply Brief)
- ☐ Proprietary Information
- ☐ Status Letter
- ☒ Other Enclosure(s) *(please identify below)*:
  Copy of Advisory Action dated 2/3/04

Remarks

SIGNATURE OF APPLICANT, ATTORNEY, OR AGENT

Firm or Individual name	Paul K. Legaard/ 38,534
Signature	
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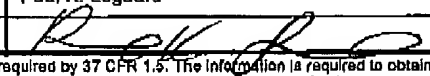
Signature		Date	June 30, 2004

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DOCKET NO.: IBIS0058-100 (IBIS-0017US) **PATENT**

RESPONSE UNDER 37 CFR 1.116
EXPEDITED PROCEDURE
EXAMINING GROUP NO. 1635

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: **Ecker, Griffey, Crooke, Sampath, Swayze, Mohan, Hofstadler, and McNeil**

Serial No.: **09/310,844** Group Art Unit: **1635**

Filed: **May 12, 1999** Examiner: **K. Lacourciere**

Title: **Molecular Interaction Sites Of Interleukin-2 RNA And Methods Of Modulating The Same**

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Dear Sir:

REQUEST FOR RECONSIDERATION

In response to the Final Rejection dated April 28, 2004 in connection with the above-identified patent application, Applicants respectfully request reconsideration.

Claims 110-113 are pending in the present application. The only remaining rejection for claims 110-113 is a provisional obviousness-type double patenting rejection as allegedly being unpatentable over claims 11, 13, 14, and 16 of co-pending application Serial No. 09/310,735 for the reasons of record in the Office Action mailed October 22, 2002.

Applicants acknowledge the provisional obviousness-type double patenting rejection set forth in the Office Action mailed October 22, 2002. Indeed, Applicants filed a response rebutting the same on December 20, 2002, which is reproduced below for the Examiner's convenience. The Advisory Action dated February 3, 2003 stated that Applicants' reply had, in fact, **overcome** the obviousness-type double patenting rejection. A copy of the Advisory Action is also provided herewith for the Examiner's convenience. Applicants' additional reply filed September 23, 2003, while correctly noting that the obviousness-type double patenting rejection had been withdrawn, incorrectly noted that the rejection was withdrawn in view of a submission of a Terminal Disclaimer. Rather, the obviousness-type double patenting rejection had been withdrawn because of Applicants' prior argument. Thus, the obviousness-type double patenting rejection should, in fact, be moot as it has already been withdrawn. The substance of the successful argument submitted in the response to the Office Action filed December 20, 2002 is presented below.

> Claims 87-93 and 110-113 were provisionally rejected under the doctrine of obviousness-type double patenting as allegedly being unpatentable over claims 11,13,14, and 16 of co-pending Application No. 09/310,735 (hereinafter, the "735 application"). The Office Action alleges that although the conflicting claims are not identical, they are not patentably distinct. Applicants traverse the rejection of claims 87-93 and 110-113 and request reconsideration thereof.
>
> An obviousness-type patenting rejection is analogous to a failure to meet the nonobviousness requirement of 35 U.S.C. § 103. *In re Braithwaite*, 154 U.S.P.Q. 29, 34 (C.C.P.A. 1967) and *In re Longi*, 225 U.S.P.Q. 645, 648 n.4 (Fed Cir. 1985). In making an obviousness-type double patenting analysis, then, the proper inquiry is as taught in *Graham v. John Deere Co.*, 383 U.S. 1 (1966). See, M.P.E.P. §804.
>
> Claims 11,13, 14, and 16 of the '735 application are drawn to compounds identified by particular methods for identifying compounds that modulate activity of target RNAs or target biomolecules. The claims of the '735 application do not recite any of the secondary structures, joined sequence length, or nucleotide sequences that are recited in the claims of the present application. Thus, the RNA molecules of the present invention, which recite secondary structures, joined sequence lengths, or nucleotide sequences are not obvious variants of the compounds claimed in the co-pending application, which fail to recite any of these elements.
>
> That an RNA molecule of the present invention may fall within the claim scope of the co-pending application is irrelevant. Indeed, a determination whether one patent

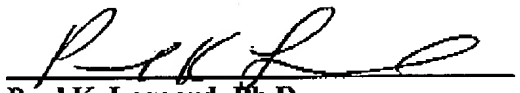
application is generic to another patent application is not the appropriate inquiry. *In re Kaplan*, 229 U.S.P.Q. 678 (Fed Cir. 1986).

Thus, that some of Applicants' compounds claimed in the present patent application may also meet limitations of claim in co-pending patent applications (of which Applicants do not concede) is not grounds for an obviousness-type double patenting rejection. It is simply a case of one patent application dominating another patent application. Domination by itself cannot support a double patenting rejection. Thus, the obviousness-type double patenting rejection is misplaced.

In view of the foregoing, Applicants respectfully request that the rejection of claims 87-93 and 110-113 under the doctrine of obviousness-type double patenting be withdrawn.

Thus, Applicants maintain that the present obviousness-type double patenting rejection has already been overcome and withdrawn. In view of the foregoing, Applicants respectfully submit that the claims are in condition for allowance. An early notice of the same is earnestly solicited. The Examiner is invited to contact Applicants' undersigned representative at (215) 665-6914 if there are any questions regarding Applicants' claimed invention.

Respectfully submitted,



Paul K. Legaard, Ph.D.
Registration No. **38,534**

Date: **30 June 2004**
Enclosure

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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/310,844	05/12/1999	DAVID J. ECKER	IBIS-0171	9454

7590 02/03/2003

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EXAMINER	
SCHMIDT, MARY M	
ART UNIT	PAPER NUMBER
1635	

DATE MAILED: 02/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

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PTO-90C (Rev. 07-01)

Advisory Action	Application No. 09/310,844	Applicant(s) Ecker et al.	
	Examiner Mary M. Schmidt	Art Unit 1635	

--The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

THE REPLY FILED 27 December 2002 FAILS TO PLACE THIS APPLICATION IN CONDITION FOR ALLOWANCE. Therefore, further action by the applicant is required to avoid abandonment of this application. A proper reply to a final rejection under 37 CFR 1.113 may only be either: (1) a timely filed amendment which places the application in condition for allowance; (2) a timely filed Notice of Appeal (with appeal fee); or (3) a timely filed Request for Continued Examination (RCE) in compliance with 37 CFR 1.114.

PERIOD FOR REPLY [check either a) or b)]

a) ☒ The period for reply expires 3 months from the mailing date of the final rejection.

b) ☐ The period for reply expires on: (1) the mailing date of this Advisory Action, or (2) the date set forth in the final rejection, whichever is later. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of the final rejection. ONLY CHECK THIS BOX WHEN THE FIRST REPLY WAS FILED WITHIN TWO MONTHS OF THE FINAL REJECTION. See MPEP 706.07(f).

Extensions of time may be obtained under 37 CFR 1.136(a). The date on which the petition under 37 CFR 1.136(a) and the appropriate extension fee have been filed is the date for purposes of determining the period of extension and the corresponding amount of the fee. The appropriate extension fee under 37 CFR 1.17(a) is calculated from: (1) the expiration date of the shortened statutory period for reply originally set in the final Office action; or (2) as set forth in (b) above, if checked. Any reply received by the Office later than three months after the mailing date of the final rejection, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

1. ☐ A Notice of Appeal was filed on _____. Appellant's Brief must be filed within the period set forth in 37 CFR 1.192(a), or any extension thereof (37 CFR 1.191(d)), to avoid dismissal of the appeal.

2. ☐ The proposed amendment(s) will not be entered because:

   (a) ☐ they raise new issues that would require further consideration and/or search (see NOTE below);

   (b) ☐ they raise the issue of new matter (see Note below);

   (c) ☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal; and/or

   (d) ☐ they present additional claims without canceling a corresponding number of finally rejected claims.

   NOTE: _____.

3. ☒ Applicant's reply has overcome the following rejection(s): *See Continuation Sheet*.

4. ☐ Newly proposed or amended claim(s) _____ would be allowable if submitted in a separate, timely filed amendment canceling the non-allowable claim(s).

5. ☒ The a)☐ affidavit, b)☐ exhibit, or c)☒ request for reconsideration has been considered but does NOT place the application in condition for allowance because: *See Continuation Sheet*.

6. ☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

7. ☒ For purposes of Appeal, the proposed amendment(s) a)☐ will not be entered or b)☐ will be entered and an explanation of how the new or amended claims would be rejected is provided below or appended.

   The status of the claim(s) is (or will be) as follows:

   Claim(s) allowed: _____.

   Claim(s) objected to: _____.

   Claim(s) rejected: *87-93 and 110-113*.

   Claim(s) withdrawn from consideration: _____.

8. ☐ The proposed drawing correction filed on _____ is a)☐ approved or b)☐ disapproved by the Examiner.

9. ☐ Note the attached Information Disclosure Statement(s)(PTO-1449) Paper No(s). _____.

10. ☐ Other: _____

Continuation of 3. Applicant's reply has overcome the following rejection(s): The double patent rejection of claims 87-93 and 110-113 over U.S. Application 09/310,735.

Continuation of 5. does NOT place the application in condition for allowance because: Applicants' arguments regarding the outstanding 35 U.S.C. 102(b) rejection of claims 87-93 over McKnight et al., 35 U.S.C. 102(b) rejection of claims 87-93 over Chen et al., 35 U.S.C. 102(e) rejection of claims 87-91 over Fu et al. (U.S. Patent 6,090,620), 35 U.S.C. 101/ 35 U.S.C. 112, first paragraph, as lacking a specific or substantial asserted utility or a well established utility and lack of enablement for making and using the claimed compositions, are similar to the arguments made in the previous response filed July 15, 2002, and the Office response herein is similar to that found in the Office action mailed 10/22/02.

The McKnight reference (rejection of claim 87-93): Applicant states the "[r]egardless of whether the cDNA sequence reported in the McKnight reference comprises the secondary structure recited in claim 87... the McKnight reference fails to teach an RNA comprising "not more than seventy nucleotides." A prior art reference anticipates a claim if every element of the claim appears in the prior art reference.... Because the cDNA sequence reported in the McKnight reference is 740 nucleotides in length, it does not anticipate claim 87 (nor dependent claims 88-93), which recites an RNA "not more than seventy nucleotides. The Office Action takes the view that due to the use of the word "comprising," the claims read on sequences that are longer than 70 nucleotides. Applicants respectfully disagree and submit that the Examiner cannot consider individual terms recited in a claim and interpret them in a vacuum."

In response, the word "comprising" is not interpreted in a vacuum, since the word is well-established as a transitional phrase in a patent claim. MPEP 211.03 states that "The transitional phrases "comprising",... define the scope of a claim with respect to what unrecited additional components or steps, if any, are excluded from the scope of the claim. The transitional term "comprising", which is synonymous with "including", "containing," or "characterized by," is inclusive or open-ended and soes not exclude additional, unrecited elements or method steps...."Comprising" is a term of art used in claim language which means that the named elements are essential, but other elements may be added and still form a construct within the scope of the claim...."comprising leaves "the claim open for the inclusion of unspecified ingredients even in major amounts."" As such, the claim is not interpreted in a vacuum, the limitation "but not more than seventy nucleotides" has not been ignored or overlooked in the process of making the art rejection using the teachings of McKnight. The claim as fully written, has first the open transitional phrase "comprising" which allows for the interpretation of the claimed subject matter to include other features not explicitly recited. The claim thus included the additional nucleic acid sequence taught by McKnight in view of the use of the transitional language "comprising". Applicant is likely also aware that the rejection was not made over claims 110-113 for instance, since the preample of those claims clearly stated the "a purified and isolated RNA fragment up to 70 nucleotides comprising...." In this case, the comprising language does not embrace the previous limiation up to 70 nucletoides and the claim is limited to compositions up to 70 nucleotides. This is not the case in the rejected claims 87-93, where the comprising language precedes, and thus allows an open interpretation of the language, "not more than 70 nucleotides."

The Chen reference and the Fu Reference (rejection of claims 87-93).: Applicant similarly points out that these references teach nucleic acid sequences that are longer than 70 nucleic acids. For the reasons given above, in view of MPEP 2111.03, the additional nucleic acid sequences taught in the Chen and Fu references are embraced by the instant claims since the instant claims 87-93 make use of the open transitional phrase, "comprising" which does not exclude additional elements, or features to the composition claimed by applicant.

The 35 U.S.C. 101/112, first paragraph, rejections of claims 110-113: Applicant's state (page 8, response filed 12/27/2002) that "The specific and substantial utility as defined in the specification is to identify "particular structural elements in eukaryotic and prokaryotic nucleic acid that are molecular interaction sites.... and methods of identifying particular structural elements in eukaryotic and prokaryotic nucleic acid, especially RNA molecules, which can interact with other molecules to effect modulation of theNRA. 'Modulation' refers to augmenting or diminishing RNA activity or expression." ... See specification, for example, page 32, 1.29 to page 33, 1.1. A specific utility is to modulate na "exemplary RNA target," for example, IL-2 mRNA for therapeutic treatment of inflammation. Se specification, e.g. Table 1, page 38, 1.9."

Upon review of these cited portions of the specification, there remains a lack of clarity in what the claims nucleic acid compostions are specifically useful for. The general assertions that they may be used for modulation of an "exemplary RNA target" does not provide specific use of the up to 70-base fragments comprising SEQ ID NOS:23-25. MPEP 2107 (II)(A)(3) states that "An invention has a well-established utility if (i) a person of ordinary skill in the art would immediately appreciate why the invention is useful based on the characteristecs of the invention (e.g., properties or applications of a product or process), and (ii) the utility is specific, substantial, and credible)." MPEP 2107 (II)(B)((3)(ii) teaches that the utility must be "well-established at the time of filing." At the time of filing, there was no guidance in either the specification or the prior art to use fragments not more than 70 bases comprising instant SEQ ID NOS:23-25 (portions of the 3' UTR of IL-2 mRNA from human, mouse and rat IL-2 mRNA), other than the knowledge of the sequences as found within the 3'UTR regions of the mouse, human and rat IL-2 mRNAs. The assertions that these sequences may be useful for modulation of "an "exemplary RNA target", and that 'Modulation' refers to augmenting or diminishing RNA activity or expression" does not allow one of ordinary skill in the art to immediately appreciate why the invention is useful based on the characteristics of the invention. There is no guidance in either the specification or the art of how to use, to enact, to employ, to practice, the modulation of any RNA target with the disclosed fragments of IL-2 mRNAs. There is no discussion in either the prior art (at the time of filing) nor the specification of how to interact these fragments, having a particular secondary structure, with any other RNA target in order to be useful in any treatment effect either. As such, the asserted use of the IL-2 fragments is not specifically, substantially or well-asserted at the time the invention was made.

The 35 U.S.C. 112, first paragraph, lack of enablement rejection, further stands since without a specific, substantial, or well-asserted utility, one of skill in the art would not have been able to make and use the invention as claimed. Applicants again state that the claimed compositions are useful for "augmenting or diminishing IL-2 mRNA expression", but as discussed above, since no such specific, substantial or well-established use of the compositions has been established, it is not clear how they would in actuality be useful for such as function as augmenting or diminishing IL-2 mRNA expression based on the teachings of the prior art and the specification as filed at the time the invention was made.

JOHN L. LeGUYADER
SUPERVISORY PATENT EXAMINER